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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,277	01/15/2002	David A. Schwartz	SOL.004.P	5923

7590

02/18/2004

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EXAMINER

NAFF, DAVID M

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/050,277

Applicant(s)

SCHWARTZ, DAVID A.

Examiner

David M. Naff

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1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 69-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 69-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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In a response of 11/21/03 to a restriction requirement of 11/17/03, applicant elected Group II claims 69-72 without traverse, and canceled claims 37-68 and 74-76.

The response canceled all non-elected claims except for claim 73.

5 Should claim 73 have been canceled?

Claim 73 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the response of 11/21/03.

10 Claims examined on the 69-72 are examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C.

15 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20

Claims 69-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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It is not readily clear where the specification discloses biomolecule/polymer conjugates as claimed. The page and lines should be pointed out where each conjugate as claimed is described.

Claim Rejections - 35 USC § 103

5 Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koster et al (6,133,436) in view of Monforte et al (6,566,055 B1) and Cook et al (5,783,682), and if necessary in further view of Mirzabekov et al (5,981,734).

10 The claim is drawn to a biomolecule/polymer conjugate wherein the biomolecule is conjugated to the polymer by a hydrazone bond, and the biomolecule is a polynucleotide, oligonucleotide, DNA or RNA, and the polymer is poly-L-lysine, poly-L-ornithine or polyethyleneimine.

15 Koster et al disclose covalently attaching nucleic acids to beads attached to a solid support (col 3, line 57 to col 5, line 4). A linking group such as polylysine (col 7, line 16) can be used to bind the beads to the support or the nucleic acid to the beads (col 7, lines 12-17).

Monforte et al disclose attaching a nucleic acid to a support using a hydrazone group (col 15, line 60).

20 Cook et al disclose using a hydrazone connection during nucleic acid synthesis on a solid support (col 10, line 25).

Mirzabekov et al disclose using a hydrazone bond to couple a label to a nucleic acid (col 4, line 39).

25 It would have been obvious to use a hydrazone bond to couple a nucleic acid to polylysine when using the polylysine to couple a

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nucleic acid to beads as disclosed by Koster et al as suggested by Monforte et al attaching a nucleic acid to a support using hydrazone group and Cook et al using a hydrazone connection during nucleic acid synthesis on a solid support. Using poly-L-lysine as the polylysine
5 would have been obvious since this is a form of polylysine that is readily available. The use of a hydrazone bond to couple a nucleic acid to a label as disclosed by Mirzabekov et al, if needed, would have further suggested using a hydrazone bond to couple a nucleic acid to the polylysine of Koster et al.

10 ***Claim Rejections - 35 USC § 103***

Claim 71 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koster et al in view of Cook et al (5,541,307).

The claim is drawn to a biomolecule/polymer conjugate wherein the biomolecule is conjugated to the polymer by a oxime bond, and the
15 biomolecule is a polynucleotide, oligonucleotide, DNA or RNA, and the polymer is poly-L-lysine, poly-L-ornithine or polyethyleneimine.

Koster et al is described above.

Cook et al disclose using oxime linkages when carrying out nucleic acid synthesis on a solid support (col 9, lines 13-21).

20 It would have been obvious to use an oxime bond to couple a nucleic acid to polylysine when using the polylysine to couple a nucleic acid to beads as disclosed by Koster et al as suggested by Cook et al using oxime linkages when carrying out nucleic acid synthesis on a solid support.

25 Claims 70 and 72 are free of the prior art.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

5 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

10 Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see [http://pair-](http://pair-direct.uspto.gov)
15 [direct.uspto.gov](http://pair-direct.uspto.gov). Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
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20 DMN
2/9/04